

REMARKS

Claims 34-106 are currently pending in the present application. Of these claims, 36-37, 40-48, 57-58, 61, 69, 76-96 and 100 have been cancelled, without prejudice to their re-filing in a divisional application, to put the present application in condition for allowance. This leaves Claims 34-35, 38-39, 49-56, 59-60, 70-75, 97-99 and 101-106 currently under consideration in the present application. All of Claims 34-35, 38-39, 49-56, 59-60, 70-75, 97-99 and 101-106 currently stand rejected. No claims are currently amended.

CLAIM REJECTIONS - 35 USC §112

The Examiner has rejected Claims 34-35, 38-39, 49-56, 59-60, 70-75, 97-99 and 101-106 under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. The Examiner states, “The limitation “laparoscopic insufflator” is not described in the specification of this application and/or the specification of US Patent 6,068,609, incorporated by reference according to the introduction section of the specification of this application. The Examiner respectfully invites the applicant to provide evidence to support the limitation in question. In view of this discrepancy, the Examiner of record will maintain the pending rejections.”

Applicants are pleased to supply the information requested by the Examiner in support of the term “laparoscopic insufflator”. As stated by the Examiner, the statutory basis for the enablement inquiry is Section 112, which states, “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his inventions.” The Federal Circuit has elaborated, “To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation.” (*Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 101, Fed. Cir. 1997). The disclosure meets the enablement requirement even if a “reasonable” amount of routine experimentation is necessary in order to practice the claimed invention, as long as such experimentation is not “undue”. (*Enzo Biochem, Inc. v. Calgene, Inc.*, 52 USPQ2d 1129, Fed. Cir. 1999).

“Whether claims are sufficiently enabled by the specification is determined as of the filing date of the patent application.” (*Enzo Biochem*, 231 USPQ 81, Fed. Cir. 1986).

Therefore, the question becomes whether the meaning of the term “laparoscopic insufflator” would be supported when the claim is read in light of the specification by one of ordinary skill in the art.

“Claim is indefinite under 35 USC §112 if those skilled in the art would not understand what is claimed when claim is read in light of the specification.” (*Morton International, Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190, CAFC 1993). This has been stated by the courts in another way. “The requirement to “distinctly” claim means that the claim must have a meaning discernable to one of ordinary skill in the art when construed according to correct principles.” (*Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 57 USPQ2d 1293, Fed. Cir. 2001). Thus, it must be determined, using acceptable principals of claim construction, whether the term “laparoscopic insufflator” would be understood by those skilled in the art.

Guidance in proper claim construction technique can be had from the case of *Edward H. Phillips v. AWH Corporation, et al.*, 75 USPQ2d 132, CAFC 2005. “Person of ordinary skill in the art, through whose eyes patent claim is construed, is deemed to read claim term not only in context of a particular claim in which disputed term appears, but in context of entire patent including specification.” *Edward H. Phillips v. AWH Corporation, et al., supra*. Thus, it can be seen that the entire specification can be looked to for aid in construing (finding support for) the term “laparoscopic insufflator”.

The Examiner has already mentioned that US Patent No. 6,068, 609 is incorporated by reference into the specification of the present application. The Examiner’s attention is also called to the fact that US Patent No. 5,411,474 is mentioned under the related art section of the present application, and is incorporated by reference in 6,068,609. A review of the entire specification would lead one to look at US Patent No. 6,068,609 and 5,411,474 to determine the meaning of the word “laparoscopic insufflator”.

“To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation” (*Genentech, Inc., supra*). Certainly, reviewing two issued United States Letters Patents involves no “undue experimentation”. Applicant now points out that all of the examples of insufflators in the specification of both patents are commercial insufflators used for laparoscopic surgery (‘474

patent, column 1, lines 35-36; column 1, line 66; column 2, line 4; column 5, line 41). These are the Karl Stroz Model 26012 and Snowden-Pencer High Flow Insufflators referenced in the specification.

To sell a medical device, a company must obtain approval from the Food and Drug Administration (“FDA”) for specific uses. Where a device is substantially equivalent to a device that has been previously approved by the FDA, a company files what is known as a 510K application with the FDA. When the FDA approves a 510K application, it approves the medical device for a specific use. Exhibit 1 comprises the 510K database entries from the FDA website for the Karl Stroz Model 26012 and Snowden-Pencer High Flow Insufflators. Both devices are classified by the FDA as “insufflator, laparoscopic”. The applicable regulation for both insufflators (Section 884.1730 -- attached as part of Exhibit 1) states, “A laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to extend it.” Thus, Applicant’s use of the term “insufflator” in its specification is precisely what it states the term should mean in the claims.

Further, reference to the specification of the present application, namely at page 1, lines 17-24, shows that the “insufflator” is used to fill the “peritoneal cavity with gas to distend it”. This creates a pneumoperitoneum. Thus, as used within the context of the specification, one of ordinary skill in the art would know that laparoscopic surgery was the type of surgery that the present invention was to be used with and a laparoscopic insufflator would be the type of insufflator used. Again, this can be deduced without “undue experimentation”.

Even if the Examiner does not consider either of the above two examples sufficient to support the term “laparoscopic insufflator” even if one of ordinary skill in the art looked in the proper dictionary one would find that the term “laparoscopic insufflator” is supported. “We have frequently stated that the words of a claim “are generally given their ordinary and customary meaning”. (*Toro Company v. White Consolidated Industries, Inc.*, 199 Fed. 3rd 1295, Fed. Cir. 1999). We have made clear moreover that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention (*Edward H. Phillips, supra.*). The Court of Appeals for the Federal Circuit has stated, “Although we have emphasized the importance of intrinsic evidence in claim construction, we have also authorized District Courts to rely on extrinsic evidence, which “consists of all evidence external to the patent in the prosecution history, including expert and

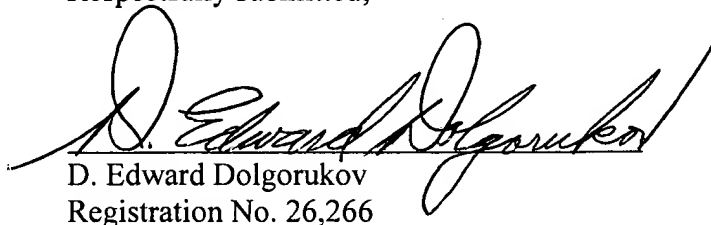
inventor testimony, dictionaries and learned treatises.” (*Markman v. Westview Instruments, Inc.*, 52 F.3d 980, CAFC 1995). “We have especially noted the help that technical dictionaries may provide to a court “to better understand the underlying technology” and the way in which one of skill in the art might use the claim terms because dictionaries, especially technical dictionaries, endeavor to collect the accepted meaning of terms used in various fields of science and technology. Those resources have been properly recognized as among the many tools that can assist a court in determining the meaning in particular terminology to those skilled in the art of the invention.” (*Edward H. Phillips, supra.*)

Thus, one of ordinary skill in the art seeking to determine the meaning of the term “laparoscopic insufflator” may look to a technical dictionary if there were no other definition in the specification. Since we are dealing with the medical field, Steadman’s Medical Dictionary, 26th Edition, is a recognized authority in the field. A copy of the definition is attached hereto as Exhibit 2. As can be seen the term “insufflator” is defined as “an instrument used in insufflation”. Insufflation is defined as “the act or process of insufflating”. “Insufflate” is defined as involving the injection of carbon dioxide into the peritoneum to achieve pneumoperitoneum during laparoscopy and laparoscopic surgery. One in the medical field would know that during laparoscopic surgery, a laparoscopic insufflator must be used to create the peritoneum. Thus, whether taken singly, jointly or collectively, the term “laparoscopic insufflator” is supported in the specification and thus, the written description requirement under 35 USC §112 is met and the present application is allowable.

Since none of the art previously cited has a laparoscopic insufflator, the Examiner is asked to remove the pending rejections, and allow the present application.

In view of the above amendments, and the remarks explanatory thereof, a favorable reconsideration of the present application, and the passing of this case to issue is courteously solicited. If the present amendments have not placed the application in condition for allowance, a telephone interview is requested to expedite the prosecution.

Respectfully submitted,



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Device Classification Name	<u>Insufflator, Laparoscopic</u>
510(K) Number	K951961
Regulation Number	<u>884.1730</u>
Device Name	KSEA MODEL 26012CH ELECTRONIC LAPAROFLATOR <u>KARL STORZ ENDOSCOPY-</u>
Applicant	<u>AMERICA, INC.</u> 600 Corporate Pointe Culver City, CA 90230 7600
Contact	Betty M Johnson
Classification Product Code	<u>HIF</u>
Date Received	04/26/1995
Decision Date	08/01/1995
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	Obstetrics/Gynecology
Statement/Summary/Purged Status	Summary Only
Type	Traditional
Reviewed By Third Party	No

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[Title 21, Volume 8]
[Revised as of April 1, 2004]
[CITE: 21CFR884.1730]



TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 884 -- OBSTETRICAL AND GYNECOLOGICAL DEVICES

Subpart B -- Obstetrical and Gynecological Diagnostic Devices

Sec. 884.1730 Laparoscopic insufflator.

(a) *Identification.* A laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter kits which include accessory instruments that are not used to effect intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b) (2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684-12720, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

Database Updated April 1, 2004



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510(k) Premarket Notification Database

Device Classification Name	<u>Insufflator, Laparoscopic</u>
510(K) Number	K920986
Regulation Number	<u>884.1730</u>
Device Name	SNOWDEN-PENCER HIGH FLOW INSUFFLATOR, SP/88- 9700
Applicant	SNOWDEN-PENCER 2058 Kilman Dr. Tucker, GA 30084
Contact	Black, Iii
Classification Product Code	<u>HIF</u>
Date Received	03/02/1992
Decision Date	06/04/1992
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Statement/Purged 510(K)
Type	Traditional
Reviewed By Third Party	No

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STEDMAN'S

Medical Dictionary

26th Edition

ILLUSTRATED IN **COLOR**



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 3 4 5 6 7 8 9 10

cardiac i., *syn heart failure* (1).
chronic adrenocortical i., *adrenocortical i.* usually as the result of idiopathic atrophy or destruction of both adrenal glands by tuberculosis, an autoimmune process, or other diseases; characterized by fatigue, decreased blood pressure, weight loss, increased melanin pigmentation of the skin and mucous membranes, anorexia, and nausea or vomiting; without appropriate replacement therapy, it can progress to acute adrenocortical i. *syn* Addison's disease, Addisonian syndrome, hyposuprarenalism, morbus Addisonii.
convergence i., that condition in which an esophoria or esotropia is more marked for far vision than for near vision.
coronary i., inadequate coronary circulation leading to anginal pain. *syn* coronarism (1).
divergence i., that condition in which an exophoria or exotropia is more marked for near vision than for far vision.
exocrine pancreatic i., lack of exocrine secretions of pancreas, due to destruction of acini; usually by chronic pancreatitis; lack of digestive enzymes from pancreas results in diarrhea, usually fatty (steatorrhea) because of lack of pancreatic enzymes.
hepatic i., defective functional activity of the liver cells.
latent adrenocortical i., *adrenocortical i.* not clinically evident but which can become severe if a sudden stress, such as an intercurrent acute illness, develops.
mitral i., *see* valvular i.
muscular i., failure of any muscle to contract with its normal force, especially such failure of any of the eye muscles.
myocardial i., *syn heart failure* (1).
parathyroid i., *syn* hypoparathyroidism.
partial adrenocortical i., normal basal adrenocortical function with failure of adrenocortical reserve to respond to ACTH stimulation.
primary adrenocortical i., *adrenocortical i.* caused by disease, destruction, or surgical removal of the adrenal cortices.
pulmonary i., *see* valvular i.
pyloric i., patulousness of the pyloric outlet of the stomach, allowing regurgitation of duodenal contents into the stomach.
renal i., defective function of the kidneys, with accumulation of waste products (particularly nitrogenous) in the blood.
respiratory i., failure to adequately provide oxygen to the cells of the body and to remove excess carbon dioxide from them.
secondary adrenocortical i., *adrenocortical i.* caused by failure of ACTH secretion resulting from anterior pituitary disease or inhibition of ACTH production resulting from exogenous steroid therapy.
thyroid i., subnormal secretion of hormones by the thyroid gland. *see also* hypothyroidism.
tricuspid i., *see* valvular i.
uterine i., atony of the uterine musculature.
valvular i., *syn* valvular regurgitation.
velopharyngeal i., anatomical or functional deficiency in the soft palate or superior constrictor muscle, resulting in the inability to achieve velopharyngeal closure.
venous i., inadequate drainage of venous blood from a part, resulting in edema or dermatosis.
in-sufflate (in-sūf'lāt). May involve injection of carbon dioxide into the peritoneum to achieve pneumoperitoneum during laparoscopy and laparoscopic surgery. [*L. in-sufflo*, to blow on or into]
in-sufflation (in-sūf-lā'shūn). 1. The act or process of insufflating. 2. *syn* inhalant (3).
perirenal i., an obsolete technique involving injection of air or carbon dioxide about the kidneys for radiography of the adrenal glands.
in-sufflator (in-sūf-lā-ter). An instrument used in insufflation.
in-su-lā, *gen.* and *pl.* in-su-lāe (in'sū-lā, -lē). 1 [NA]. An oval region of the cerebral cortex overlying the extreme capsule, lateral to the lenticular nucleus, buried in the depth of the fissura lateralis cerebri (sylvian fissure). *syn* insular area, insular cortex, island of Reil. 2. *syn* island. 3. Any circumscribed body or patch on the skin. [*L. island*]

Haller's i., a doubling of the thoracic duct for part of its course through the thorax. *syn* Haller's annulus.

in-su-lar (in'sū-lār). Relating to any insula, especially the island of Reil.

in-su-late (in'sū-lāt). To prevent the passage of electric or radiant energy by the interposition of a nonconducting substance. [*L. insulatus*, made like an island]

in-su-lation (in-sū-lā'shūn). 1. The act of insulating. 2. The nonconducting substance so used. 3. The state of being insulated.

in-su-lator (in'sū-lā-ter). A nonconducting substance used as insulation.

in-su-lin (in'sū-lin). A polypeptide hormone, secreted by beta cells in the islets of Langerhans, that promotes glucose utilization, protein synthesis, and the formation and storage of neutral lipids; obtained from various animals and available in a variety of preparations, i. is used parenterally in the treatment of diabetes mellitus. [*L. insula*, island, + -in]

biphasic i., the specific antidiabetic principle of the pancreas of the ox in a solution of that from the pancreas of the pig.

globin i., *syn* regular i.

globin zinc i., a sterile solution of i. modified by the addition of zinc chloride and globin; it contains 40 or 80 units per ml; duration of action is about 18 hours.

human i., a protein that has the normal structure of i. produced by the human pancreas, prepared by recombinant DNA techniques and by semisynthetic processes.

immunoreactive i. (IRI), that portion of i. in blood measured by immunochemical methods for the hormone; presumed to represent the free (unbound) and biologically active fraction of total blood i.

isophane i., a modified form of i. composed of i., protamine, and zinc; an intermediately acting preparation used for the treatment of diabetes mellitus. *syn* NPH i.

lente i., *syn* insulin zinc suspension.

NPH i., *syn* isophane i. [*Neutral Protamine Hagedorn*]

protamine zinc i., i. modified by the addition of protamine and zinc chloride; it contains 40 or 80 units per ml.

regular i., a rapidly acting form of i. which is a clear solution and may be administered intravenously as well as subcutaneously; may be mixed with longer acting forms of i. to extend the duration of effect. Onset of effect occurs in ½ to 1 hour, peak effects are observed in 2 to 3 hours, and the duration of effect is about 5 to 7 hours. *syn* globin i.

semilente i., *syn* prompt insulin zinc suspension.

ultralente i., a form of zinc precipitated i. in suspension in which the particle size is large, and thus release into the bloodstream after subcutaneous injection is slow; it can be mixed with other i.'s having different particle sizes to achieve different durations of activity. Can be derived from porcine, bovine, or genetically engineered human type.

in-su-li-ne-mia (in'sū-li-nē-mē-ā). Literally, insulin in the circulating blood; usually connotes abnormally large concentrations of insulin in the circulating blood. [insulin + *G. haima*, blood]

in-su-lin-o-gen-e-sis (in'sū-lin-ō-jen'ē-sis). Production of insulin. [insulin + *G. genesis*, production]

in-su-lin-o-gen-ic, **in-su-lo-gen-ic** (in'sū-lin-ō-jen'ik, in'sū-lō-jen'ik). Relating to insulinogenesis.

in-su-li-no-ma (in'sū-li-nō-mā). An islet cell adenoma that secretes insulin. *syn* insulinoma.

in-su-li-tis (in'sū-lī'tis). Inflammation of the islands of Langerhans, with lymphocytic infiltration which may result from viral infection and be the initial lesion of insulin-dependent diabetes mellitus. [*L. insula*, island, + -itis, inflammation]

in-su-lo-ma (in'sū-lō-mā). *syn* insulinoma. [*L. insula*, island, + -oma, tumor]

in-sult (in'sūlt). An injury, attack, or trauma. [*L. insultus*, fr *L. insulto*, to spring upon]

in-sus-cep-ti-bil-i-ty (in'sū-sep'ti-bil'i-tē). *syn* immunity. [*L. suscipio*, pp. -ceptus, to take upon one, fr. *sub*, under, + *capio*, to take]

int. cib. Abbreviation for *L. inter cibos*, between meals.